

AD _____

Award Number: DAMD17-99-1-9576

TITLE: Roundtable on Biomedical Engineering Materials and
Applications

PRINCIPAL INVESTIGATOR: Richard Chait, Ph.D.

CONTRACTING ORGANIZATION: National Academy of Sciences
Washington, DC 20418

REPORT DATE: September 2000

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
Distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20010124 100

DTIC QUALITY INSPECTED 4

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE September 2000	3. REPORT TYPE AND DATES COVERED Annual (1 Sep 99 - 31 Aug 00)	
4. TITLE AND SUBTITLE Roundtable on Biomedical Engineering Materials and Applications			5. FUNDING NUMBERS DAMD17-99-1-9576	
6. AUTHOR(S) Richard Chait, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) National Academy of Sciences Washington, DC 20418 E-MAIL: rchait@nas.edu			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; Distribution unlimited				12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words)				
14. SUBJECT TERMS				15. NUMBER OF PAGES 6
				16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified		20. LIMITATION OF ABSTRACT Unlimited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
298-102

Biomedical Engineering and Materials Applications (BEMA) Roundtable Progress Report

Summary

The National Materials Advisory Board held the first BEMA Roundtable meeting on 20-21 July 2000 at The National Academies, Main Building Board Room, Washington DC. Attendees represented government, industry, and academia. Four speakers spoke on three topics: 1) The Appropriate Determination of Biocompatibility, 2) Improving the Scientific Basis for Regulatory Decision Making, and 3) Supply and Access of Biomaterials.

Based on the briefs presented at this roundtable, three specific, priority topics emerged: 1) Science Based Testing, 2) Partnerships to Improve the Regulatory Process, and 3) Barriers to Innovation in Medical Devices. To kick off discussion of these topics, three pairs of members volunteered to write concept papers, eventually leading to the focus of a June 2001 workshop.

The BEMA members also decided to add a fourth, catch-all topic, "Other Emerging Topics".

The BEMA members also requested creation of a members-only, interactive website for use in planning future workshops and roundtables, and to foster discussion on the four topics above. The members agreed to hold the next roundtable on 5-6 December 2000 in Washington DC. This roundtable will be a planning meeting to finalize the topics for the June 2001 workshop and discuss possible topics for a Fall 2001 workshop.

Since the first BEMA Roundtable, Medtronic Inc has decided to join the BEMA Roundtable. In addition, Zimmer Inc, a manufacturer of orthopedic devices, and a wholly-owned subsidiary of Bristol-Myers Squibb, has expressed interest in joining the BEMA Roundtable.

Finally, NMAB has drafted an agenda for the December 2000 BEMA Roundtable meeting. Scheduled speakers include Dr. David Feigal, Director for the Center for Devices and Radiological Health, US Food and Drug Administration; Prof Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University; Prof Henry Rack, Department of Ceramic and Materials Engineering, Clemson University; and Mark Heller, Senior Partner, Hale and Dorr LLP.

Introduction

The National Materials Advisory Board held the first BEMA Roundtable meeting on 20-21 July 2000 at The National Academies, Main Building Board Room, Washington DC. The roundtable was held under the combined auspices of the National Research Council, National Academy of Engineering, and Institute of Medicine. An Academy roundtable is a convening mechanism for dialogue and exchange of information among individuals, including government officials, who represent all sides of particular, broad-based issues of public policy. This provides a structured opportunity for the exchange of information

and the identification of concerns in a nonadversarial setting among government, industry, and academe. The roundtable will not provide advice or recommendations on any specific issue or policy pending before any government agency.

With respect to BEMA, the roundtable provides a forum for identifying major opportunities for applying engineering principles to create and improve clinical performance of medically useful materials and devices, including implants, as well as for discussion of strategies for overcoming obstacles—technical, legal, or cultural—that impede transition of new materials and devices to clinical application.

Roundtable Attendees and Agenda

Roundtable attendees included:

Government Agencies

- Food and Drug Administration
- National Institutes of Health
- National Institute of Standards and Technology
- National Science Foundation
- U.S. Army (WRAIR)
- U.S. Navy (ONR)
- Veterans Administration

Industry

- Advanced Tissue Sciences
- Boston Scientific
- Dow Chemical
- Edwards Lifesciences
- Advanced Medical Technology Association (AdvaMed), formerly HIMA
- Johnson & Johnson
- MiniMed, Inc.

Academia

- Alfred University
- California State University Program for Education and Research in Biotechnology (CSUPERB)
- Center for Innovative Minimally Invasive Therapy (CIMIT)
- National Academy of Engineering (NAE)
- New Jersey Associated Institutions for Material Sciences (AIMS)
- University of Florida

The agenda covered the following:

Panel I—The Appropriate Determination of Biocompatibility

Speaker: Joachim Kohn (Director, The New Jersey Center for Biomaterials)

Panel II—Improving the Scientific Basis for Regulatory Decision Making

Speaker: Kshitij Mohan (Senior Vice President & Chief Technology Officer, Boston Scientific Corporation)

Panel III—Supply and Access of Biomaterials

Speakers: Paul Citron (Vice President of Science & Technology, Medtronic, Inc), Rachel Kaganoff Stern (Associate Political Scientist, RAND)

Action Items

Based on the briefs presented at this roundtable, three specific, priority topics emerged:

<u>Topic</u>	<u>Concept Paper Authors</u>
Science Based Testing	Goldstein (Alfred)/Sahatjian (Boston Scientific)
Partnerships to Improve the Regulatory Process	Rekow (AIMS)/Rosen (CIMIT)
Barriers to Innovation in Medical Devices	Scopelianos (J&J)/Johnson (Dow)

To kick off the topic discussion, the authors listed above will write concept papers, eventually leading to the focus of a June 2001 workshop.

The BEMA members also requested creation of an interactive website for member use in planning future workshops and roundtables. The members also agreed to hold the next roundtable on 5-6 December 2000 in Washington DC. This roundtable will be a planning meeting to finalize the topics for the June 2001 workshop and discuss possible topics for a Fall 2001 workshop.

The BEMA members also added a fourth, catch-all topic, "Other Emerging Topics". All four topics will be discussed on the interactive web site.

Additional Developments

Medtronic Inc has joined the BEMA Roundtable. Medtronic is a leading medical device manufacturer, producing products such as pacemakers, defibrillators, drug delivery systems, and neurostimulation systems. Paul Citron, Medtronic's VP of Science and Technology, was an invited speaker at the first BEMA Roundtable meeting in July 2000.

NMAB board member Prof Earl Dowell of Duke University provided contact information for Prof Jim Mason, a faculty member in Aerospace and Mechanical Engineering at Notre Dame. Prof Mason is also a consultant to Zimmer Inc, a manufacturer of orthopedic devices, and a wholly-owned subsidiary of Bristol-Myers Squibb. Zimmer has expressed interest in joining the BEMA Roundtable.

NMAB has a draft agenda for the December 2000 BEMA Roundtable meeting. Scheduled speakers include Dr. David Feigal, Director for the Center for Devices and

Radiological Health, US Food and Drug Administration; Prof Henry Piehler, Department of Materials Science and Engineering, Carnegie-Mellon University; Prof Henry Rack, Department of Ceramic and Materials Engineering, Clemson University; and Mark Heller, Senior Partner, Hale and Dorr LLP.